K063060

510(k) Summary

Submitter:	Blueshine Sr.l. – Unipersonale Via Olivi, 2 30171 Mestre VE/Italy Ph. 0039 041 5055847
Facility description:	Placed on 500 m^2, Blueshine Company is divided in accounting, commercial and technical departments, wares receipt and storage areas, warehouse, hydraulic, electronic, optical assembly areas, final test area and shipping division. The production, for some part, is in outsourcing, receiving half-assemblied and assemblied products from its suppliers.
Contact:	Ms. Alice Novelli Quality and Certification Dept.
Date Summary Prepared:	May 23, 2006
Device Trade Name:	Blueshine Light Shine system
Common Name:	Pulsed Light System
Classification Name:	Instrument, surgical, powered, laser 79-GEX 21 CFR 878.410
Equivalent Device:	Radiancy (Israel) Ltd Skinstation system, cleared for commercial distribution by the FDA on June 19, 2003 under 510(k) notification No. K030897 and Sciton, Inc. Profile BBL system cleared for commercial distribution by the FDA on November 11, 2003 under 510 (k) notification No. K032460
Device Description:	The Blueshine Light Shine System is a pulsed light, wavelength range adjustable system. It provides selectable handpiece aperture sizes for a variety of applications Light emission activation is by foot switch. Overall weight of the system is 110lbs., and the size is 57x56x98cm (LxWxH). Electrical requirement is 110 VAC, 16A, 50-60 Hz, single phase.

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Intended Use:	The Blueshine Light Shine is intended for permanent hair reduction, photocoagulation of dermatological vascular lesions, photothermolysis of blood vessels (treatment of facial and leg veins), and treatment of benign pigmented lesions and inflammatory acne (acne vulgaris) It can be used for all skin types, from I (subjects with white skin, freckles, blond or red hair, blue or green eyes) to VI (subjects with brown to dark skin/ brown or black hair/ brown eyes included suntanned skin).
Comparison:	The Blueshine Light Shine system has similar indications for use, the same principle of operation, and essentially the same wavelength range and pulse energy range as the predicate devices.
Nonclinical Performance Data:	None
Clinical Performance Data:	None
Conclusion:	The Blueshine Light Shine system is a safe and effective device for the indicated uses.
Additional Information:	none

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Blueshine SRL
c/o Mark Job
Regulatory Technology Services, Inc.
1394 25th Street, NW
Buffalo, MN 55313

NOV 2 9 2006

Re: K063060
Trade/Device Name: Blueshine Light Shine Systems: SP, Twin, and Compact SP
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: November 13, 2006
Received: November 14, 2006

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276- 0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (If known):_____

Device Name: Blueshine Light Shine systems: SP, Twin and Compact SP

Indications For Use:

The Blueshine Light Shine system is indicated for permanent hair reduction, photocoagulation of dermatological vascular lesions, photermolysis of blood vessels (treatment of facial and leg veins), and treatment of benign pigmented lesions.

It is also indicated for treatment of inflammatory acne (acne vulgaris).

Prescriptive Use____X____OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use_____. (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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